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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mark Ashby

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

IZAGUIRRE, ISMAEL

ART UNIT

PAPER NUMBER

3765

MAIL DATE

DELIVERY MODE

01/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/621,670	Applicant(s) ASHBY ET AL.	
	Examiner Ismael Izaguirre	Art Unit 3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-41 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-24 and 38-41 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, 13, 25, 27-34 and 44-48 is/are rejected.
- 7) ☒ Claim(s) 2, 7-12, 26 and 35-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner is appreciative of the changes made to the language of the claims. These have been duly noted and considered. After a further careful consideration of newly found prior art and a reconsideration of the art of record, the following is submitted for applicant's consideration:

CLAIMS

Summary

Claims 1, 6, 14, 25, 38, 44 and 45 are the independent claims under consideration in this Office action.

Claims 2, 3, 5, 7-13, 15-24, 26-37, 39-41 and 46-48 are the dependent claims under consideration in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 32, there is no proper antecedent basis for the words "the delivery catheter".

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6 and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cope (4,405,314).

Cope teaches an apparatus useful for inhibiting blood loss out a puncture site in a blood vessel wall and for indicating the location of a blood vessel. Cope teaches a catheter for use with a procedure within the renal pelvis. This apparatus is however useful when it would be used with a procedure involving the field of blood vessels. The apparatus includes a vent tube 12 having a lumen passing through the center thereof and where the vent tube is connected to a control head 10. The control head is useful for passing around and over a guiding wire movable within a blood vessel. The guiding wire is first located using a needle and then the needle is retracted and the control head with vent tube would be passed over the wire. Passing the distal end of the tapered control head through the blood vessel past the lateral hole 21 would inhibit bleeding out the blood vessel and would mark the wall location when the bleeding would stop. The control head is provided with a central lumen which extends from a distal port 15 to the lumen at the distal portion of the vent tube. The lateral hole 21 is provided for communicating the control head lumen with an outside of the control head. This hole is large enough to redirect and introduce a wire 32 therethrough.

Claims 25, 27-34 and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Janzen (5,437,631).

Janzen teaches an apparatus for sealing puncture wounds and positioning a pledget on the outer wall of a blood vessel. Janzen teaches a control head 28 or 32 with a lumen in its distal end which accommodates a locating wire 22 which is movable within the blood vessel. An assembly which accommodates a pledget 48, is positionable over the control head and includes a pusher 50 for positioning the pledget material onto the outer wall of the blood vessel. Janzen teaches the method steps of advancing the pledget material with the control head still within the vessel. The pledget is moved forward and the control head is retracted (figure 6). Then, the delivery cannula 41 and the control head are retracted while holding the pusher in place and then the entire assembly is retracted while the pledget is pushed and compresses into position for sealing the hole in the blood vessel.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (6,090,130).

Nash et al. teach an apparatus useful for inhibiting blood loss out a puncture site in a blood vessel wall and for indicating the location of a blood vessel. Nash et al. teach a catheter for use with a procedure within a blood vessel. This apparatus is useful for inserting a wire, balloon or stent within the blood vessel. The apparatus includes a vent tube 28D (figure 27, for example) having a lumen passing through the center thereof and including a valve 28E. The vent tube is connected to a control head 28B. The control head is useful for passing a wire out of and into a blood vessel. The guiding wire is located using a positioning device 300 and then the control head is passed over the wire and positioning device. The control head is provided with a central lumen which extends from a distal port at 28C to the lumen of the vent tube. A lateral hole 304 is provided for communicating the control head lumen with an outside of the control head. This hole provides a means for marking the blood vessel wall when the control head is at the blood vessel wall. As the control head is moved in and out or as the guide 300 is moved in and out, blood loss is started and stopped and this would mark the vessel wall as the blood would spurt out the valve 28E in the vent tube.

ALLOWABLE SUBJECT MATTER

Claims 14-24 and 38-41 are allowable over the prior art of record.

Claims 2, 7-12, 26 and 35-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

INQUIRIES

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ismael Izaguirre whose telephone number is (571) 272-4987. The examiner can normally be reached on M-F (8:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Welch can be reached on (571) 272-4996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ismael Izaguirre/
Primary Examiner, Art Unit 3765